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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/938,689	08/23/2001	Manley Huang	9342-028	3530

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EXAMINER	
NGUYEN, QUANG	
ART UNIT	**PAPER NUMBER**
1636	9

DATE MAILED: 12/17/2002

Please find below and/or attached an Office communication concerning this application or proceeding.

Offic Action Summary	Application No.	Applicant(s)	
	09/938,689	HUANG ET AL.	
	Examiner	Art Unit	
	Quang Nguyen, Ph.D.	1636	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period f r Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☐ Responsive to communication(s) filed on _____ .

2a)☐ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-28* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☐ Claim(s) _____ is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☒ Claim(s) *1-28* are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

11)☐ The proposed drawing correction filed on _____ is: a)☐ approved b)☐ disapproved by the Examiner.

If approved, corrected drawings are required in reply to this Office action.

12)☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

13)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____ .

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

14)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).

a) ☐ The translation of the foreign language provisional application has been received.

15)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____ .
4) ☐ Interview Summary (PTO-413) Paper No(s). _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other:

DETAILED ACTION

Claims 1-28 are pending in the present application.

Election/Restrictions

Restriction to one of the following inventions is required under 35 U.S.C. 121:

Group Restriction:

I. Claims 1-8 and 11-16, drawn to a recipient mouse comprising a disruption in both alleles of a gene such that lymphocyte maturation does not occur, and exogenous transgenes that encode cytokines, and a method of making a mouse lacking in mature T and B lymphocytes and comprising exogenous cytokines, wherein the transgenes are introduced through pronuclear transfer, classified in class 800, subclasses 18, 24.

II. Claims 1-7, 9 and 11-16, drawn to a recipient mouse comprising a disruption in both alleles of a gene such that lymphocyte maturation does not occur, and exogenous transgenes that encode cytokines, and a method of making a mouse lacking in mature T and B lymphocytes and comprising exogenous cytokines, wherein the transgenes are in an embryonic stem cell, classified in class 800, subclasses 18, 25.

III. Claims 1-7 and 10-16, drawn to a recipient mouse comprising a disruption in both alleles of a gene such that lymphocyte maturation does not occur, and exogenous transgenes that encode cytokines, and a method of making a mouse lacking in mature T and B lymphocytes and comprising exogenous cytokines, wherein the transgenes are introduced through

breeding with a mouse comprising the transgenes, classified in class 800, subclasses 18, 22.

IV. Claims 17-28, drawn to a recipient mouse comprising a disruption in both alleles of a gene such that lymphocyte maturation dos not occur; and a human transgene comprising a nucleic acid sequence that encodes a MHC Class II DR3 molecule, wherein the transgene comprises naturally linked DRab and DQab alleles, and methods for making the same recipient mouse, classified in class 800, subclasses 18 and 21.

Claims 7 and 11-16 link a plurality of patentably distinct methods of producing a mouse lacking in mature T and B cells and comprising exogenous cytokines that lack the unity of invention. This is because the methods of producing the transgenic mouse by introducing the transgenes through pronuclear transfer (claim 8), through the transgenes in an embryonic stem cell (claim 9), and through breeding with a mouse comprising the transgenes (claim 10) involve different starting materials, different method steps and different technical considerations for attaining the transgenic mouse. The methods of Groups I-III can be carried out independently one from the other. As set forth in MPEP 803.02, unity of invention exists if all species recited in a claim (1) shows a common utility, and (2) share a substantial structural feature disclosed as being essential to that utility. Thus, claims 7 and 11-16 are improper written as linking claims linking multiple distinct inventions. Applicant is required under 35 U.S.C. 121 to elect the invention of Group I, II or III.

The inventions are distinct, each from the other because of the following reasons:

Although there are no provisions under the section for "Relationship of Inventions" in M.P.E.P. § 806.05 for inventive groups that are directed to different methods, restriction is deemed to be proper because the methods in Groups I to IV appear to constitute patentably distinct inventions. With respect to the methods of Groups I to III, they are patentably distinct for the same reasons already stated above. Basically, these methods of producing the transgenic mouse involve different starting materials, method steps and different technical considerations for attaining the transgenic mouse. For example, the method of Group I requires the introduction of the transgenes through pronuclear transfer, whereas the method of Group II requires the introduction of the transgenes in an embryonic stem cell, and the method of Group III requires the introduction of the transgenes through breeding with a mouse comprising the transgenes. The methods of Groups I to III can be carried out independently one from the other.

The recipient mouse of either Groups I to III is unrelated, chemically and structurally distinct from the recipient mouse of Group IV. The recipient mouse of Group I to III does not require to contain a human transgene that encodes a MHC Class II DR3 molecule, wherein the transgene comprises naturally linked DRab and DQab alleles, whereas the recipient mouse of Group IV does not require to contain transgenes encoding exogenous cytokines. Therefore, the methods of Groups I to III are also distinct from the method of Group IV because they involve different method steps, starting materials and different technical considerations for obtaining different recipient mice that are chemically and structurally distinct.

Because these inventions are distinct for the reasons given above and have acquired a separate status in the art because of their recognized divergent subject matter, and separate search requirements, it would be unduly burdensome for the examiner to search and/or consider the patentability of all the inventions in a single application. Therefore, restriction for examination purposes as indicated is proper.

Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a diligently-filed petition under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17 (h).

Species Restriction:

Should Applicants elect the invention of either Groups I, II or III, claims 4-6 are directed to the following patentably distinct species: (a) a recipient mouse comprising exogenous transgenes that encode cytokines comprising IL-7, SCF and LIF, (b) a recipient mouse comprising exogenous transgenes that encode cytokines comprising GM-CSF, M-CSF and IL-6, (c) a recipient mouse comprising transgenes that encode cytokines comprising IL-7, SCF, LIF, GM-CSF, M-CSF and IL-6.

Applicant is required under 35 U.S.C. 121 to elect a single disclosed species for prosecution on the merits to which the claims shall be restricted if no generic claim is finally held to be allowable. Currently, claims 4-6 7-11 and 15-16 are generic.

Applicant is advised that a reply to this requirement must include an identification of the species that is elected consonant with this requirement, and a listing of all claims readable thereon, including any claims subsequently added. An argument that a claim is allowable or that all claims are generic is considered nonresponsive unless accompanied by an election.

Upon the allowance of a generic claim, applicant will be entitled to consideration of claims to additional species which are written in dependent form or otherwise include all the limitations of an allowed generic claim as provided by 37 CFR 1.141. If claims are added after the election, applicant must indicate which are readable upon the elected species. MPEP § 809.02(a).

Should applicant traverse on the ground that the species are not patentably distinct, applicant should submit evidence or identify such evidence now of record showing the species to be obvious variants or clearly admit on the record that this is the case. In either instance, if the examiner finds one of the inventions unpatentable over the prior art, the evidence or admission may be used in a rejection under 35 U.S.C. 103(a) of the other invention.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Quang Nguyen, Ph.D., whose telephone number is (703) 308-8339.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's mentor, Gerald Leffers, Jr., Ph.D., may be reached at (703) 305-6232, or SPE, Irem Yucel, Ph.D., at (703) 305-1998.

Any inquiry of a general nature or relating to the status of this application should be directed to LIE, Tiffany Tabb, whose telephone number is (703) 605-1238.

Quang Nguyen, Ph.D.

TERRY MCKELVEY
PRIMARY EXAMINER